DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 5, 2001, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.
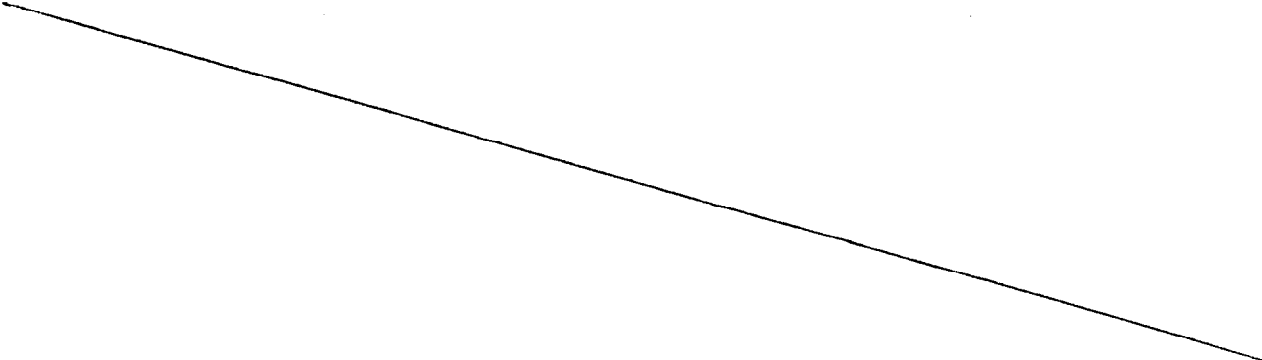
Agenda: On March 5, 2001, the committee will hear updates on: (1) The Laboratory of Immunobiochemistry personnel, (2) lot release statistics, (3) new guidance documents, (4) research and standardization programs, and (5) a compliance report. The committee will discuss whether master seed stocks of mold strains used for allergenic extracts should be rederived to reduce a theoretical risk of transmissible spongiform encephalopathy transmission. The committee will also discuss the statistical power of clinical studies used to assess bioequivalence as it applies to allergen extract studies. In the afternoon, the committee will discuss particulates that appear in allergen

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extracts and the effect of these particulates on the safety and efficacy on these products. In closed session, the committee will receive a report on the status of an investigational new drug application and product license application supplement.

Procedure: On March 5, 2001, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 17, 2001. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:40 a.m., and between approximately 2:40 p.m. and 3:10 p.m. on March 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 21, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On March 5, 2001, from approximately 3:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of these materials.

FDA regrets that it was unable to publish this notice 15 days prior to the March 5, 2001, Allergenic Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Allergenic Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: _____2/14/01_____
    February 14, 2001

_____Bonnie H. Malkin_____

Bonnie H. Malkin,
Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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Domonie Oliver